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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,095	09/11/2007	Huimin Kong	BH-003-PUS	8867
28986	7590	03/24/2010	EXAMINER	
HARRIET M. STRIMPEL, D. Phil. New England Biolabs, Inc. 240 COUNTY ROAD IPSWICH, MA 01938-2723			BABIC, CHRISTOPHER M	
			ART UNIT	PAPER NUMBER
			1637	
			NOTIFICATION DATE	DELIVERY MODE
			03/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/594,095	Applicant(s) KONG ET AL.	
	Examiner CHRISTOPHER M. BABIC	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/25/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 1-19, in the reply filed on February 10, 2010 is acknowledged. Thus, the restriction requirement is still deemed proper and hereby made FINAL. As such, claim(s) 20 -22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 19. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "T7-like" is a relative term which renders the claims indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In other words, it is unclear what characteristic constitutes a "T7-like" characteristic or to what degree a sum of characteristics constitutes a "T7-like" species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 5-8, 12-15, 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Auerbach (U.S. 5,354,668).

Auerbach teaches a method for amplifying a target DNA sequence in a circular DNA (cDNA) (fig. 8B; col. 23, for example), comprising: (a) providing the cDNA template (fig. 8B, teaches a double stranded circular DNA molecule, for example); (b) adding to the cDNA template: (i) a first sequence-specific DNA primer that hybridizes to one strand of the cDNA (fig. 8B, teaches forward primer complementary to A strand, for example); (ii) a second sequence-specific DNA primer that is substantially identical to a portion of the one strand of the cDNA (fig. 8B, teaches reverse primer complementary to

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A' strand, for example); and (iii) a helicase preparation, a DNA polymerase and dNTPs (col. 7 and 11, teaches helicase, T7 DNA polymerase, and dNTPs, for example); (c) synthesizing primer extension products to produce: (i) a plurality of copies of the target DNA sequence defined by the first and second primers; and (ii) a plurality of copies of a concatamer derived from the cDNA including the target; and (d) amplifying the target DNA sequence (abstract, teaches amplification under isothermal conditions; as understood by the examiner, the reaction of fig 8B and col. 23 would necessarily produce both products due to the presence of both a forward and reverse primer).

2. Claims 1-4, 6-8, and 12-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomas (WO 02/068683 A2; 6 September 2002).

Thomas teaches a method for amplifying a target DNA sequence in a circular DNA (cDNA) (abstract; fig. 2; pg. 7-8, CRCA, for example), comprising: (a) providing the cDNA template (fig. 2, teaches a single stranded circular DNA molecule, for example); (b) adding to the cDNA template: (i) a first sequence-specific DNA primer that hybridizes to one strand of the cDNA (fig. 2, teaches forward primer complementary to circular strand, for example); (ii) a second sequence-specific DNA primer that is substantially identical to a portion of the one strand of the cDNA (fig. 2, teaches reverse primer complementary to first product from circular DNA, for example); and (iii) a helicase preparation, a DNA polymerase and dNTPs (pg. 14-15, teaches helicase, T7 DNA polymerase, and dNTPs, for example); (c) synthesizing primer extension products to

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produce: (i) a plurality of copies of the target DNA sequence defined by the first and second primers; and (ii) a plurality of copies of a concatamer derived from the cDNA including the target; and (d) amplifying the target DNA sequence (pg. 15, teaches amplification under isothermal conditions @ about 25°C; as understood by the examiner, the reaction of fig. 2 and pg. 7-8 would necessarily produce both products due to the presence of both a forward and reverse primer).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Auerbach (U.S. 5,354,668) or Thomas (WO 02/068683 A2; 6 September 2002) in view of Mendez et al. (BioEssays, 2003, vol. 25, pages 1158-1167).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach hexameric helicases.

Mendez provides a supportive disclosure that teaches a method of amplification involving hexameric helicases (page 1163, col. 1, para. 2, for example).

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Thus, in summary, it is submitted that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to incorporate hexameric helicases into the methods of Auerbach or Thomas since Mendez demonstrates such chemicals as useful for increasing the efficiency of nucleic acid amplification reaction.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 814-880-9945. The examiner can normally be reached on Monday-Friday 10:00AM to 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Primary Examiner
Art Unit 1637
Technology Center 1600